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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,454	03/22/2005	Augustinus Bader	LORWER P33AUS	7961
20210	7590	09/20/2005	EXAMINER	
DAVIS & BUJOLD, P.L.L.C. FOURTH FLOOR 500 N. COMMERCIAL STREET MANCHESTER, NH 03101-1151			FORD, ALLISON M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,454	<b>Applicant(s)</b> BADER, AUGUSTINUS	
	<b>Examiner</b> Allison M. Ford	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 31-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 31-60 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |




## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 31-49, drawn to a method for culturing cells on a cell culture chamber comprising three layers: a support structure on which the cells are cultured, an intermediate layer, and an external boundary layer which is impermeable to the cells.

Group II, claim(s) 31-42 and 46-52, drawn to a method for culturing cells on a cell culture chamber comprising two layers: a support structure on which the cells are cultured and an external boundary layer which is impermeable to the cells; wherein the method comprises exposure of the cell culture chamber to liquid or gas pressure.

Group III, claim(s) 31-42, 46-49 and 53-54, drawn to a method for culturing cells on a cell culture chamber comprising two layers: a support structure on which the cells are cultured and an external boundary layer which is impermeable to the cells; wherein the cell culture chamber is incorporated into a nutrient circuit.

Group IV, claim(s) 55-58, drawn to an apparatus for culturing cells, comprising a support structure and a boundary layer external to the support structure; and wherein the apparatus is inserted into a nutrient circuit.

Group V, claim(s) 55 and 57-59, drawn to an apparatus for culturing cells, comprising a support structure, a boundary layer external to the support structure, and a container with at least one pressure connection for connection to a pressure source.

Group VI, claim(s) 60, drawn to a support structure.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 60, at least, is anticipated by or obvious over Applegate et al (US Patent 5,843,766). Applegate et al teach a porous mesh substrate for growing cell layers (which applicant calls a support structure), wherein the substrate is enclosed within a growth chamber casing which is impermeable to the

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cells (See Applegate et al, abstract & col. 5, ln 56-col. 6, ln 13). Consequently, the special technical feature which links claims 31-60, a porous support structure for culturing cells in a cell layer, formed of a porous material and furnished externally with a boundary layer which is impermeable to cells, does not provide a contribution over the prior art, so unity of invention is lacking.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

**Boundary layer material:** a) hydrogel (claim 37); b) alginate polymerized in a calcium chloride solution (claim 38); c) overgrowth of cells (claim 39); d) a detachable material (claim 48); e) a soluble material (claim 48); f) a vascularized material (claim 48); g) a prevascularized material (claim 48).

**Intermediate layer material:** h) lipid layer (claim 44); I) glycoproteins (claim 44); j) protein (claim 44); k) biodegradable layers (claim 44); l) removable layers (claim 44); m) liquid polymers (claim 45); n) viscous polymers (claim 45).

Applicant is required, in reply to this action, to elect a single species from each listing to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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The following claim(s) are generic: Claim 31 (generic to boundary layer material) & Claim 43 (generic to intermediate layer material).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2), the species are not art recognized equivalents.

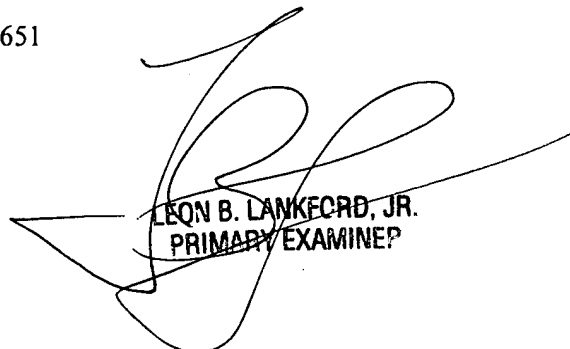
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford  
Examiner  
Art Unit 1651

  
LEON B. LANKEFORD, JR.  
PRIMARY EXAMINER